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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,959	06/25/2001	Richard Ian Christopherson	DAVI139.001C1	2583

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,959	CHRISTOPHERSON ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,2 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1, 2 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/2/06 KAC
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 19 are amended. Claims 22 and 23 have been canceled. Claims 1, 2 and 18-21 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 2, 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al (JACS, 1995, Vol. 117, pp. 12050-12057) in view of the Becton Dickenson Acute Leukemia Phenotyping Kit, 1992, pages 1-57) is maintained for reasons of record.

Claim 1 is drawn to a method for identifying a leukemic T cell, B cell or myeloid lineage cell in a human subject comprising contacting a biological sample comprising leukocytes with an array of immunoglobulin molecules immobilized on a solid support, wherein the array comprises 7 to about 1000 immunoglobulins, wherein the immunoglobulin molecules are specific for cell surface marker antigens, wherein the cell surface marker antigens comprise at least seven cell surface marker antigens selected from the list in Table 4, and wherein the cell surface marker antigens distinguish leukemias of T cell, B cell or myeloid lineage, and determining which cell surface marker antigens have bound to which immobilized immunoglobulin molecules to establish a differential pattern of binding that identifies a leukemia that is of T, B or myeloid lineage. Claim 2 embodies the method of claim 1 wherein the immunoglobulin molecules are monoclonal antibodies. Claims 20 embodies the method of claim 1, wherein the biological sample is blood. Sundberg et al teach a general method of immobilizing antibodies at precise locations on solid supports, which include glass microscope slides (page 12050, second column, second paragraph and page 12053, under the heading of "Photodeprotection of Caged Biotin Derivatized Slide"). Sundberg et al teach that the technique is amenable for creating a patterned array with a high degree of spatial orientation (page 12050, first column, lines 7-13 under the heading of "Introduction"). Sundberg et al suggest that the technique will be useful in diagnostics (abstract, last two lines). Sundberg et al do not teach the diagnosis of leukemia or the detection of leukemic cells by using the patterned array of antibodies.

Beckton Dickinson teach a kit comprising 12 monoclonal antibodies (two control antibodies, anti-CD10, CD19, CD20, CD5, CD3, CD22, CD7, CD33; CD13 and anti-HLA-DR, page 4), which meets the limitation of 7 to 1000 immunoglobulins and patterns of antibody binding which are indicative of various types of leukemias including T cell and myeloid leukemias (see page 1 under "Intended Use" and Table 4, page 44) . Becton Dickenson teach the staining of cells by two antibodies at a time and the separation of antibody pairs by separate tubes for analysis by flow cytometry . It is noted that Becton-Dickenson teaches the detection of leukemia in a human subject (second paragraph of "intended use" on page 1). Becton Dickenson do not teach the use of a patterned antibody array comprising said monoclonal antibodies.

It would have been prima facie obvious at the time the claimed invention was made to use the antibodies taught by Becton Dickenson to be indicative of leukemic cells as a patterned array taught by Sundberg et al. One of skill in the art would have been motivated to do so in order to eliminate the expense of the flow cytometer. One of skill in the art would understand that all the antibodies can be made into a patterned array on the surface of a microscope slide for a single image analysis, eliminating the need for performing a separate flow cytometric analysis on all seven tubes as dictated by Becton-Dickenson. Thus, sampling error and processing time is decreased, and the requirement for purchasing/maintaining a flow cytometer is eliminated, making the diagnosis faster and more economical.

The rjection of claims 1, 2, 18, 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Sudberg et al (JACS, 1995, Vol. 117, pp. 12050-12057) and the Becton Dickenson Acute Leukemia Phenotyping Kit, 1992 as applied to claims 1, 2, 19, 20 and 22 above, and in further view of Paul (Fundamental Immunology, (text) 1993, page 460) is maintained for reasons of record.

Claim 18 embodies the method of claim 1 wherein the immunoglobulins are polyclonal. Paul teaches the advantages of polyclonal antibodies over monoclonal antibodies in diagnostics. It would have been prima facie obvious at the time the clamed invention was made to substitute polyclonal antibodies for the monoclonal antibodies which bind to the cell surface antibodies

taught by the Becton Dickenson. One of skill in the art would have been motivated to do so by the teachings of Paul.

The rejection of claims 1, 2, 19-2 under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al (JACS, 1995, Vol. 117, pp. 12050-12057) and the Becton Dickenson Acute Leukemia Phenotyping Kit, 1992 as applied to claims 1, 2, 19 and 20 above, and in further view of Terstappen et al (US6265150) is maintained for reasons of record.

Claim 21 embodies the method of claim 19 wherein the immunoglobulin molecules are antigen binding fragments of immunoglobulin molecules.
Terstappen et al teach a method of rapidly obtaining human antibodies against known and novel surface antigens in their native configuration, expressed on phenotypically defined subpopulations of cells from wherein the library of phage particles expressing Fab or single chain Fv (scFv) antibody fragments (claims 1 and 6), wherein said method is a subtracting procedure and does not depend on immunization procedures or the necessity to repeatedly construct phage antibody libraries (abstract).

It would have been prima facie obvious at the time he claimed invention was made to use a library of phage particles expressing Fab or single chain Fv (scFv) antibody fragments to identify phage particles which bind to the cell surface antigens taught by Becton Dickenson to be diagnostic for leukemia. One of skill in the art would have been motivated to do so in order to clone phage which will be a renewable source of antibody fragments which bind to the antigens require in the patterned array without immunization procedures or repeated construction of antibody libraries.

Applicant argues that applicant argues that the combination of references fails to teach an array comprising 7 to 1000 immunoglobulins. This has been considered but not found persuasive. The kit of the Becton Dickenson Acute Leukemia Phenotyping Kit and the methods taught by the publication indicate the use of 12 antibodies as stated above, which fulfills the specific embodiment of 7 to 1000. Applicant argues that the combination of references fails to establish the identity of a T-cell or B cell or myeloid lineage leukemia comprising establishing a differential pattern of density binding on an array. this has been considered but not found

persuasive. There is ample motivation to combine the references to establish an array comprising all twelve antibodies of the kit. The resulting addressable array would result in a pattern of differential binding density on the array. Applicant argues that when Sundberg et al teach the binding of antibodies to a support, Sundberg is describing only the binding of two different antibodies to a flow cell. This has been considered but not found persuasive. While Sundberg et al demonstrates the binding of two antibodies to a solid support, Sundberg et al by no means limits the invention to only two antibodies. Sundberg teaches that it is necessary to cap the residual biotin molecules and then block the additional biotin binding sites by flooding with excess biotin. Sundberg et al teaches that the 500 um X 500 um array is only one example of a spatially localized array limited only by the contrast and resolution of the lithographic procedure and that higher resolution, allowing for a denser array, would be obtained by using thinner glass slides or printing on the front surface .

Applicant argues against the use of Paul as a reference stating that no description of the superiority of polyclonal antibodies over monoclonal antibodies can be found in the cited text. Paul states that polyclonal may be more specific than any one of its clonal parts and thus may be more useful because of the mutispecific nature of the antiserum (page 460, second paragraph under "Polyclonal versus Monclonal").

Applicant argues that Tertappen et al fail to teach or suggest a method for identifying a leukemia of T cell, B cell or myeloid lineage. This has been considered but not found persuasive. Terstappen et al is not relied upon for the antibodies used to diagnose the specific leukemias. Terstappen is relied upon for the technology of making phage display immunoglobulin libraries that meet the limitation of claim 21.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Canella, Ph.D.
8/6/2006

KAREN A. CANELLA PH.D
PRIMARY EXAMINER